

the analysis was restricted to patients who had received  $\geq 4$  prescriptions in the 6 months prior to their first lansoprazole 15 mg prescription (25%: 31/122). Amongst those patients with a specific diagnosis of GORD/RO, 37% (15/41) switched to a higher dose PPI within 6 months. Around half (52%; 16/31) of patients who returned to a higher dose had no specific reason recorded (16/31). However the most commonly recorded reason for failing on lansoprazole 15 mg was inadequate control of symptoms (35%; 11/31). **CONCLUSION:** The proportion of patients changed from standard or high dose PPI to lansoprazole 15 mg who required an increase in PPI therapy within 6 months was higher than that reported for patients treated with esomeprazole 20 mg.

**PGS3**

### **META-ANALYSIS OF PPI-BASED TRIPLE THERAPY FOR THE ERADICATION OF *HELICOBACTER PYLORI***

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**OBJECTIVE:** The recommended treatment for *Helicobacter pylori* eradication in the UK is a proton pump inhibitor (PPI) in combination with amoxicillin 1 g and clarithromycin 500 mg all twice daily for 7 days. The aim of this analysis was to compare the efficacies of the recommended PPI-based triple therapies for the eradication of *H. pylori* using omeprazole-based triple therapy as a common comparator. **METHODS:** The PPIs licensed in the UK for twice daily triple therapy are esomeprazole 20 mg (EAC), lansoprazole 30 mg (LAC), omeprazole 20 mg (OAC), pantoprazole 40 mg (PAC), and rabeprazole 20 mg (RAC). A meta-analysis of randomised controlled trials comparing a 7-day regimen of PPI-based triple therapies was conducted using omeprazole-based triple therapy as a common comparator. Data on eradication rates were extracted and re-analysed, where required, to provide "intention-to-treat" results. The primary method of calculating the summary effect estimates used a Fixed Effects model. A chi-squared test was used to assess heterogeneity for each comparison. A secondary analysis comparing 7-day regimens of PPI plus any dose of amoxycillin and clarithromycin was conducted to test the robustness of the results. **RESULTS:** The alternative strategies, compared with OAC, provided the following results—EAC (Relative Risk 1.01; 95% Confidence Interval: 0.95 to 1.08), LAC (RR 1.05; 95% CI: 0.94 to 1.17), PAC (RR 0.92; 95% CI: 0.80 to 1.06). No trials comparing rabeprazole with omeprazole using UK recommended triple therapy were found. Significant heterogeneity was detected in the LAC comparison with OAC and so these results should be treated with caution. The secondary analysis confirmed that there was no significant difference in the four alternative strategies compared to OAC. **CONCLUSIONS:** No PPI-based triple therapy was found to be significantly more efficacious than omeprazole-based triple therapy. However, esomeprazole 20 mg is the only PPI licensed in the UK for triple therapy that would be considered a low dose.

**PGS4**

### **ESOMEPRAZOLE AS MAINTENANCE THERAPY IN EROSIIVE ESOPHAGITIS: A QUANTITATIVE ASSESSMENT OF EFFICACY USING AN EVIDENCE-BASED APPROACH**

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**OBJECTIVE:** Evidence-based techniques were applied to clinical trial data of esomeprazole for maintaining healed erosive esophagitis (EE) to provide a practical, quantitative analysis of its efficacy relative to lansoprazole. **METHODS:** Patients with a history of heartburn and EE, Los Angeles Grade A–D at baseline, received esomeprazole 40 mg once daily for up to 8 weeks for healing. Those with healed EE were randomized to receive once daily esomeprazole 20 mg (n = 615) or lansoprazole 15 mg (n = 609) for up to 6 months. For this retrospective analysis, the number needed to treat (NNT), the reciprocal of the absolute risk reduction (ARR), was calculated at 6 months for all patients and for subgroups with mild disease (LA Grade A or B) and severe disease (LA Grade C or D). **RESULTS:** In this evidence-based analysis, it was determined that 11 patients with EE would need to be treated with esomeprazole to prevent one treatment failure that otherwise may occur with lansoprazole regardless of the baseline grade of EE. As the severity of disease increased (LA Grade C or D), the NNT to prevent one relapse that may otherwise have occurred with lansoprazole decreased to 6. **CONCLUSIONS:** For patients with more severe disease, the NNT was lower, indicating a greater likelihood of therapeutic success with esomeprazole versus lansoprazole. This evidence supports esomeprazole as an effective treatment for maintenance of remission and prevention of treatment failure in gastroesophageal reflux disease patients with EE.

### **GASTROINTESTINAL DISORDERS—Cost Studies**

**PGS5**

### **ECONOMIC BURDEN OF IRRITABLE BOWEL SYNDROME (IBS): ONE YEAR RESULTS. RITMO STUDY**

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**OBJECTIVE:** Estimate the burden of IBS comparing resource use between IBS-patients (IBSp) and non-IBS subjects (controls) during a 1-year follow up. **METHODS:** Observational, prospective study including 517 IBSp, meeting Rome II criteria, and 84 controls. Controls were selected from those subjects who had attended a health centre due to digestive problems (excluding IBS). Both samples were selected from the consulting offices of 92 Spanish gastroenterologists and Primary Care Physicians. IBSp and controls attended a total of 5 visits at 3 month intervals. During first month after each visit patients recorded drug utilization and indirect resource in a diarycard. Direct resource was collected by investigators in follow-up medical controls. **RESULTS:** Mean patients age (SD) was 43 (14) years and 75% were female. No differences in age and gender were observed between IBSp and controls. 90% of IBSp and 100% of controls visited a clinic at least once ( $p < 0.01$ ), but only IBSp (52%) did it due to abdominal pain. Hospitalizations were registered in 7.5% of IBSp and 2.9% of controls. Thirty-eight percent of IBSp and 15% of control were assisted in an emergency guard at least once ( $p < 0.01$ ); abdominal pain was the main reason for IBSp to attend the emergency guard (11%). 43% of IBSp required some specific test due to their abdominal pathology (blood samples, gastroscopy or colonoscopy). Mean patient cost associated with resources used was much higher in IBSp (€413.39) than in controls (€143.94) ( $p < 0.01$ ). In terms of indirect resources, 59% of IBSp and 26% of controls experienced limited or reduced performance at work ( $p < 0.01$ ). Mean patient cost associated with absence from work at one year was also much higher for IBSp (€502.21€) than for controls (€109.70) ( $p < 0.01$ ). **CONCLUSIONS:** This prospective 1-year follow-up study confirms that IBS is associated with an important burden in terms of direct and indirect costs and that IBSp use more health resources and experience higher productivity loss compared with non-IBS.

## PGS6

**COST EFFECTIVENESS OF CONTINUOUS AND ON-DEMAND THERAPY WITH ESOMEPRAZOLE 20 MG IN PATIENTS WITH SYMPTOMATIC GASTROESOPHAGEAL REFLUX DISEASE (GERD): THE ONE STUDY**

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**OBJECTIVE:** The primary objective of this multicenter, randomised, open study was to assess the difference in direct medical costs incurred over a 6-months period with a 20 mg esomeprazole on-demand maintenance strategy, compared to a 20 mg q.d. continuous therapy. Secondary objectives were to assess GERD symptoms and to measure patient satisfaction during the maintenance phase. **METHODS:** In total, 2884 patients with uninvestigated GERD entered the study and received esomepra-

zole 40 mg q.d for 4 weeks. At the end of the acute treatment phase 93% patients were symptom free (complete resolution of heartburn or not more than 1 day with mild heartburn during the last 7 days prior to the visit), and were randomised to receive either continuous or on-demand treatment (esomeprazole 20mg) during a 6-month maintenance phase (1315 and 1325 patients respectively). Analyses were performed on an intention to treat basis. Direct costs include study, OTC and other GERD medication, unscheduled visits and GERD tests. **RESULTS:** The proportion of patients heartburn free at 6 months was significantly higher ( $p < 0.001$ ) in the continuous treatment with esomeprazole 20 mg (86.1%) than in the on demand group (78.0%). Patient's satisfaction reached 94% after the 4 weeks acute treatment and remained 92% in the maintenance phase, similar in both groups. Both treatment arms were well tolerated. Mean daily direct costs were significantly lower ( $P < 0.001$ ) in the on demand group (€0.96  $\pm$  0.54 SD) than in the esomeprazole 20 mg q.d. arm (€1.39  $\pm$  0.31 SD). The proportion of patients taking GERD-related drugs was similar in the two groups (8.0% vs 7.3%,  $p = 0.6$ ). **CONCLUSIONS:** Continuous or on-demand treatment in patients with uninvestigated GERD offer effective and safe symptom control with a high patient satisfaction. On-demand treatment allows significant reduction in medical costs. Choice of treatment should be considered on patient basis.

## PGS7

**COST ANALYSIS OF A NEW PROPOSAL FOR REIMBURSEMENT OF PROTON PUMP INHIBITOR TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE (GERD) IN BELGIUM**

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**OBJECTIVES:** To compare the pharmaceutical costs of a new proposal of reimbursement of proton pump inhibitors (PPI) in the treatment of GERD with the present regulation in which PPI's are reimbursed only when endoscopy demonstrates esophagitis. The new reimbursement proposal includes empiric therapy (without endoscopy), symptomatic treatment of non-erosive GERD, and chronic "on-demand" therapy. **METHODS:** A decision tree model was developed for treatment of patients with GERD resistant to H2 receptor antagonists. Calculations were performed using MS Excel. Response rates of different therapies and probabilities of findings at endoscopy were derived from literature. Costs from the payer's perspective were calculated for the first 48 weeks of treatment using the mean price of the PPI on the Belgian market on Jan 1st 2003. **RESULTS:** The present reimbursement system and the new proposal represented a mean 48 weeks cost per case of respectively €351 and €204. Sensitivity analysis